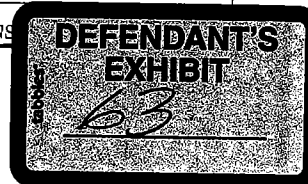


# **EXHIBIT 63**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069	DATE(S) OF INSPECTION 09/18/2006 - 10/11/2006* FEI NUMBER 3003450194
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Divya Patel, President	
FIRM NAME Actavis Totowa LLC	STREET ADDRESS 4 Taft Road
CITY, STATE, ZIP CODE, COUNTRY Totowa, NJ 07512-1006	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Packager, Labeler and Tester
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>	
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</p> <p style="text-align: right;">RELEASE REVIEWED: <u>SAB</u> <u>ghap</u> C.O. DATE</p>	
LABORATORY CONTROL SYSTEM	
OBSERVATION 1	
<p>Deviations from written specifications, test procedures, and laboratory mechanisms are not justified.</p> <p>Specifically, upon receipt of atypical data in the analytical laboratory, re-tests are performed without invalidating the original results. In addition, the results of re-testing are reported and original results are ignored. For example:</p> <p>a) After receiving a "high dissolution value" of 117.3% drug dissolved for tablet # 5 in the dissolution testing of Benzotropine Mesylate Tablets USP, 2 mg (13-week accelerated stability), no assignable cause could be identified and the analysis was re-performed with freshly prepared standard and sample solutions. The original results were ignored and the re-test results were reported.</p> <p>b) "Suspect test results" in the related substance testing of Oxycodone and Acetaminophen Tablets, USP 2.5 mg / 325 mg (Batch # RBR 2467, 100 and 1000 packs, 8 week accelerated stability), were attributed to the 0.45 µm filter used to filter the sample solution. The sample chromatogram for the 1000 pack size contained unknown peaks at 4.6, 8.41, and 9.87 minutes and the sample chromatogram for the 100 pack size had a peak at the expected retention time of [REDACTED] (b)(4) of 0.6% (specification is NMT [REDACTED]). These results were received on 4/27/06, but no investigation was (b)(4) initiated until 5/17/06, in which the results were reported as "suspect test results" rather than "out of specification results". The filter study completed on 5/31/06 provides an explanation for unknown peaks at approximately 4.46, 8.34, and 9.52 minutes, when the filter is not pre-conditioned, but not for a peak appearing at the expected retention time of [REDACTED] (about 26.87 minutes). The original results were discarded and the repeat test results were reported. (b)(4)</p> <p>c) When "comparatively lower" results were received during the related substances testing of Hydromorphone Hydrochloride Tablets USP, 8 mg, RBR 1239 at the 6-month room temperature stability test point, an investigation could find no cause to the out of trend data. The 6-month room temperature samples (both 100 and 500 packs) were re-tested, were found within the typical trend and were reported without invalidating the original results.</p> <p>d) In the testing of Isradipine Capsules, USP 2.5 mg, RBR 1865 for chromatographic purity at the 12-month room temperature test point, the BP Impurity D value for both 60 count and 500 count bottles were found "significantly less</p>	
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FORM FDA 483 (07/00)	PREVIOUS EDITION OBSOLETE
INSPECTIONAL OBSERVATIONS	



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<p>compared to the previous stability stations." The investigation was inconclusive, the samples were re-tested and re-testing results were found to be comparable with the previous stability station results. The results of re-testing were reported without invalidating the original results.</p>		
<p><b>OBSERVATION 2</b></p> <p>The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established.</p> <p>Specifically, there is no assurance that methods are appropriate for use due to repeated testing without invalidating original out of specification data obtained during method validations. For example:</p> <p>a) The accuracy &amp; precision study was repeated in the method validation of related compounds testing for Imipramine Hydrochloride Tablets, 50 mg, however the original out of specification accuracy results for Imipramine Hydrochloride and Desipramine Hydrochloride were not invalidated.</p> <p>b) The linearity &amp; range study was repeated in the method validation of dissolution testing for Phendimetrazine Tartrate Tablets USP, 35 mg, however the original out of specification results for percentage bias were not invalidated.</p> <p>c) The accuracy &amp; precision study was repeated in the method validation of related substances testing for Buspirone Hydrochloride, API, however the original out of specification accuracy results for Impurity-C were not invalidated.</p> <p>d) The accuracy &amp; precision study was repeated in the method validation of related substances testing for Bzotropine Mesylate, API, however the original out of specification accuracy results for Diphenylmethane were not invalidated.</p>		
<p><b>OBSERVATION 3</b></p> <p>Verification of the suitability of the testing methods is deficient in that they are not performed under actual conditions of use.</p> <p>Specifically, there is no assurance that equipment is adequately cleaned due to the deficiencies in cleaning validation studies. For example:</p> <p>a) Cleaning validation was performed for the process trains of the following products without evaluating for sample</p>		
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